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IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MILTON A. BASS
BASS & ULLMAN
Attorneys for Petitioner
Par Pharmaceutical, Inc.
747 Third Avenue
New York, New York 10017
(212) 751-9494

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ARGUMENT

Merck & Co., Inc. ("Merck") states in opposition to the Petition that the issues below are too "fact-bound" to warrant review and that the decision below is not contrary to *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982). This statement is entirely incorrect. In fact, Par Pharmaceutical, Inc. ("Par") was found liable under a rule of law contrary to *Inwood*.

In this case, the district court made findings of fact that Par had three legitimate reasons to use blue and white capsules for its version of indomethacin. The court found that these advantages of imitation provided benefits to patients and health care professionals. Par does not quarrel with these findings; nor apparently does Merck. There is thus no "fact-bound" dispute in which the Petition seeks to embroil the Court.

The issue in this case is a legal one. The holding of the lower courts resulted from the application of an incorrect legal standard of what constitutes functionality. The rule of law in the lower court was that a trade dress feature is not functional as a matter of law if a competitor can enter the market without imitation. Merck seeks to obfuscate this issue by claiming that the findings below were subject to a "clearly erroneous" standard of review. The ultimate ruling of nonfunctionality, however, involves a mixed question of law and fact. In reviewing the Second Circuit decision on functionality in *Inwood*, this Court itself drew the distinction, stating:

> "If the District Court erred as a matter of law, the Court of Appeals should have identified the District Court's legal error. If the Court of Appeals disagreed with the District Court's factual findings, it should not have dismissed them without finding them clearly erroneous." *Inwood v. Ives*, 456 U.S. at 857 n.20.

Whether patients obtain benefits unrelated to source identification by virtue of trade dress imitation is indeed a question of fact subject to the "clearly erroneous" standard. Whether such benefits establish functionality, however, is a question of law.

Merck also asserts that the new standard of law below governing functionality does not conflict with *Inwood*. This is grossly inaccurate. In *Inwood*, the brand-name company tried to make an important issue of the fact that competitors could and had for some time sold generic substitutes without imitating the trade dress. Brief for the Respondent at pp. 11-12; 21; 45. The issue was even addressed at some length at oral argument.

Despite the existence of these non-imitative generics, the Court upheld the *Inwood* district court ruling of functionality based upon the same findings of legitimate advantages as those found by the district court here. The *Inwood* holding and the rule of law applied by the courts below cannot both be correct.

Merck's argument that there is no conflict between this case and *Inwood* is without merit. In opposing the Petition, Merck asserts that the only difference between this case and *Inwood* is that the two district courts simply made different findings. This is untrue. The two district courts made the same findings of fact as to the legitimate reasons for and advantages of imitation. The real difference between this case and *Inwood* is that the district courts applied two entirely different rules of law as to what constitutes functionality for prescription drug trade dress.

Merck further contends that Par is urging a rule that would preclude a district court from considering evidence of nonfunctionality. This is also incorrect, for Par would have welcomed an opportunity below to address evidence that special circumstances applied to INDOCIN. If, for example, Merck showed that no other drug should be taken concurrently with indomethacin, and that therefore patients would not commingle indomethacin, it could vitiate that element of trade dress functionality. The undisputed record here, though, is just the opposite. Merck introduced no evidence that special circumstances applied, and indeed INDOCIN is precisely a product for which continuity of color should be maintained.[1]

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[1] In Point II of the Petition, Par also showed that the Third Circuit improperly applied the " 'watered-down' and incorrect" standard of reasonble anticipation. In response, Merck asserts a meaningless semantic point, claiming that there was not only reasonable anticipation of passing off, but "actual expectation" of it. When *Inwood* requires an act of intentional inducement, the new term "expectation" cannot rationally support liability anymore than "anticipation" did. Merck further argues that *Sears-Compco* "left undisturbed state laws

(footnote continued)

Finally, Par wishes to make clear that the dispute over the legal standard of functionality raised in this case involves significant social consequences for the industry and the public, particularly the elderly and the poor. The injunction which Merck succeeded in obtaining below has a very real and undesirable effect on the market for prescription drugs.

By virtue of the decisions below, patients who want to use the blue and white color of indomethacin as a means of assuring themselves that they are getting the right medication, irrespective of source, can purchase only Merck's product. Patients who commingle a number of drugs and who rely upon the appearances of those drugs to know which to take at a particular time can purchase only Merck's product if they want to avoid mistakes and confusion. Hospitals and nursing homes that want to avoid dispensing errors and patient confusion and anxiety when a generic substitute is dispensed in an unfamiliar color can purchase only Merck's product.

When Par is enjoined from meeting the legitimate demand for these non-source benefits of color continuity, it is placed at an unfair competitive disadvantage. Patients are forced to pay higher prices for a product which is subject to an improper court-ordered monopoly.

Par respectfully believes that such a result is entirely beyond the proper scope of protection afforded by Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), and an indirect obstruction to state and federal laws encouraging generic substitution.

Having succeeded below, Merck naturally argues that these issues are fact-bound and undeserving of Supreme Court review. The real view of the brand-name industry, however, was presented

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of unfair competition." Merck Brief at p. 21. This is not correct. In those very cases, the Court limited the scope of state laws of unfair competition. As Par has demonstrated in its Petition, what *Sears-Compco* prohibits state law from doing — imposing liability where there is imitation, but no act of deception — is exactly what was done below.

to this Court in *Inwood*. At that time, the Pharmaceutical Manufacturers Association, of which Merck was, and is, a leading member, said to this Court:

> "We submit, however, that this [functionality] is not an issue of fact, to be decided anew—and perhaps inconsistently—in each case. The same issue arises in every 'look-alike' case, and the arguments presented do not vary according to the particular drug at issue. It would be irrational to hold that the result in each case depends upon how a particular fact-finder happens to evaluate the particular record made on these matters of general applicability. There must ultimately be one rule as to whether 'look-alike' generic drugs serve any legitimate purpose." Brief of the Pharmaceutical Manufacturers Association as Amicus Curiae at pp. 14-15 [footnotes omitted].

Par shares this view of the PMA. Resolution of the color issue would be in the interest of the pharmaceutical industry, the government and the consuming public. Merck's position would lead only to continued litigation and uncertainty. Par respectfully urges the Court to review the judgment of the Third Circuit. In light of the conflict between the lower courts and the *Inwood* decision, Par believes that if this issue is to be finally settled, it is of such public importance as to warrant a review on the merits.

CONCLUSION

For the foregoing reasons, and for the reasons set forth in the Petition of Par, we respectfully request that a Writ of Certiorari be issued to review the judgment below.

Respectfully submitted,

MILTON A. BASS
BASS & ULLMAN
Attorneys for Petitioner
Par Pharmaceutical, Inc.
747 Third Avenue
New York, New York 10017
(212) 751-9494

Of Counsel
LAWRENCE H. ROTH